

JAN 15 2004



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**510(K) SUMMARY  
OF SAFETY AND EFFECTIVENESS**

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Safety and Effectiveness for the use of the ADVANCE® Double High Insert.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 15, 2003
Contact Person:	Katie Logerot Regulatory Affairs Associate
Proprietary Name:	ADVANCE® Double High Insert
Common Name:	Tibial Insert
Classification Name and Reference:	21 CFR 888.3560 Knee, Patellofemorotibial, Semi-constrained, cemented, Polymer/ metal/polymer
Device Product Code and Panel Code:	Orthopedics/87/ JWH

**DEVICE INFORMATION**

**A. INTENDED USE**

The ADVANCE® Double High Insert is indicated for use in knee arthroplasty for reduction or relief of pain and/or improved knee function in skeletally mature patients with the following conditions:

- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and
- 4) treatment of fractures that are unmanageable using other techniques.

**B. DEVICE DESCRIPTION**

The design features of the ADVANCE® Double High Insert are summarized below:

- Manufactured from UHMWPE
- Offered in left and right designs, sizes 0-6, thicknesses of 10mm-25mm
- Allows for medial-pivot rotation

**headquarters**

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- Allows for the retention of the cruciate retaining ligament
- Allows for higher flexion

#### **C. SUBSTANTIAL EQUIVALENCE INFORMATION**

The indications for use and materials of the ADVANCE® Double High Insert are identical to the ADVANCE® Medial Pivot Insert and AXIOM® Standard Tibial Insert. The articulating surface of the ADVANCE® Double High Insert is substantially equivalent to the ADVANCE® Medial Pivot Insert and AXIOM® Standard Tibial Insert. The safety and effectiveness of the ADVANCE® Double High Insert are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 15 2004

Ms. Katie Logerot  
Regulatory Affairs Associate  
Wright Medical Technology, Inc.  
5677 Airline Road  
Arlington, Tennessee 38002

Re: K033890

Trade/Device Name: ADVANCE® Double High Insert  
Regulation Number: 21 CFR 888.3560  
Regulation Name: Knee joint patellofemoral tibial polymer/metal/polymer semi-constrained  
cemented prosthesis  
Regulatory Class: II  
Product Code: JWH  
Dated: December 15, 2003  
Received: December 16, 2003

Dear Ms. Logerot:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

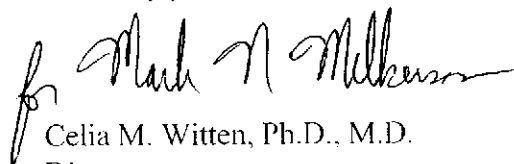
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Donna Heraty

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is fluid and cursive, with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K033890

Device Name: ADVANCE® Double High Insert

### Indications For Use:

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- 1) noninflammatory degenerative joint disease including osteoarthritis, traumatic arthritis, or avascular necrosis;
- 2) inflammatory degenerative joint disease including rheumatoid arthritis;
- 3) correction of functional deformity;
- 4) revision procedures where other treatments or devices have failed; and
- 5) treatment of fractures that are unmanageable using other techniques.

The ADVANCE® Double High Insert is for single cemented use.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark N. Melker*  
Mark N. Melker  
Division of General, Restorative  
and Neurological Devices

510(k) Number: K033890

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